

**REMARKS**

Claims 1-3 and 21 remain in this application. Claims 1 and 3 have been amended. New claims 22-24 have been added, and are supported by disclosure at pages 8-9 of the specification, as filed. No new matter has been added. Applicants respectfully request reconsideration in view of the following remarks.

**Applicants' Response to Rejections under 35 U.S.C. §112**

Claims 1-3 and 21 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants have amended claims 1 and 3 to change "said discrete domains are extracted" to "said extractable polymeric material is extracted," as suggested by the Examiner. Accordingly, Applicants respectfully submit that the Section 112 rejection has been overcome and should be withdrawn.

**Applicants' Response to Rejections under 35 U.S.C. §102**

**U.S. Patent No. 5,141,522 to Landi**

Claims 1 and 3 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,141,522 to Landi (hereinafter "Landi"). Applicants respectfully traverse the rejection on the basis that Landi fails to disclose each and every element of Applicants' claims.

The Examiner contends that Landi discloses a medical device, particularly a vascular graft, which is a tubular extrudate. The Examiner further contends that the medical device is an interpenetrating polymer network of a PTFE matrix having discrete domains of an extractable polymeric material distributed therein. According to the Examiner, Landi also teaches that upon exposure to a dissolving medium or degradation temperature, the polymer is extracted from the matrix to create pores.

Landi is directed to a composite material used for repairing mammalian tissue. The composite contains two biocompatible polymers. The first polymer is non-absorbable, unsintered PTFE, which is used in the composite as a reinforcing binder. The second polymer is a bioabsorbable polymer, which enhances tissue growth.

With respect to the first polymer component, Landi teaches that PTFE may be blended with a molten thermoplastic polymer, such as polymethylmethacrylate ("PMMA"). According to Landi, the PMMA component may be extracted from PTFE. Nowhere in Landi, however, is it disclosed, taught, or suggested that PMMA forms an interpenetrating polymer network ("IPN") with PTFE.

An IPN is commonly understood in the art to mean a polymer containing two or more polymer networks, which are at least partially interlaced but not covalently bonded to each other. *See* IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY (2<sup>nd</sup> ed. 1997), exhibit attached. More specifically, an IPN is a combination of two polymers in which at least one is synthesized and/or crosslinked in the immediate presence of the other to form an interlaced network. *See* U.S. Patent No. 4,764,560 to Mitchell; Col. 1, lines 63-66. Accordingly, a mixture of two or more separate and independently pre-formed polymer networks is not an IPN. *See* IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY.

Landi discloses a mixture of PTFE and a molten thermoplastic polymer, i.e., PMMA. This is a mixture of two separate, and pre-formed, polymer networks. Nowhere in Landi is it disclosed, taught, or suggested that these two polymers are interlaced or interpenetrating in any manner. As commonly understood in the art, and defined above, Landi's combination of PTFE and PMMA cannot be considered an IPN.

Applicants' claims 1 and 3 require an IPN of PTFE and another extractable polymer. Because Landi fails to disclose such a recitation, it cannot anticipate Applicants' claims. It is well settled that to be an effective anticipatory reference, a cited document must disclose each and every limitation recited in a claim under examination. Failing such precise disclosure, such

a cited document must fail as an anticipatory reference. Therefore, Landi does not anticipate Applicants' claims 1 and 3, and Applicants respectfully request reconsideration and withdrawal of this rejection.

**U.S. Patent No. 6,540,780 to Zilla et al.**

Claims 1 and 3 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,540,780 to Zilla et al. (hereinafter "Zilla"). Applicants respectfully traverse the rejection on the basis that Zilla fails to disclose each and every element of Applicants' claims.

The Examiner contends that Zilla discloses a medical device, specifically a vascular graft, which is a tubular extrudate. The Examiner further contends that the medical device is an IPN of polyurethane and PTFE interpenetrating each other, and having an extractable polymeric material distributed therein. According to the Examiner, Zilla teaches that upon exposure to a dissolving medium or degradation temperature, the polymer is extracted from the matrix to create pores.

Zilla discloses graft material that requires thermoplastic elastomers, preferably polyurethanes. Helical channels are formed in the graft by including extractable fibers in the graft material. Zilla also discloses that the graft material may contain additional, non-extractable fibers for reinforcement, such as PTFE. Nowhere in Zilla, however, is it disclosed, taught, or suggested that any of these components, particularly polyurethane and PTFE, form an IPN. Contrary to the Examiner's allegations, Zilla does not provide nor even suggest that these two polymers are interpenetrating in any manner. Rather, Zilla discloses a combination of PTFE fibers and polyurethane graft material. Addition of PTFE fibers occurs, for example, by winding the PTFE fibers onto a mandrel with the graft material, or including them with polyurethane oriented fibers for melt extrusion. Such disclosure is merely a combination of two separate polymer networks, and therefore, not an IPN as described above.

Because Zilla fails to disclose, teach, or suggest an IPN including PTFE and another

extractable polymeric component, it cannot anticipate Applicants' claims. As such, Applicants respectfully request reconsideration and withdrawal of this rejection.

**U.S. Patent No. 4,764,560 to Mitchell**

Claims 1, 3 and 21 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,764,560 to Mitchell (hereinafter "Mitchell"). Applicants respectfully traverse the rejection on the basis that Mitchell fails to disclose each and every element of Applicants' claims.

The Examiner contends that Mitchell discloses a medical device, specifically a vascular graft, which is a tubular extrudate. The Examiner further contends that the tubular extrudate is an IPN of PTFE and an extractable polymer. According to the Examiner, Mitchell teaches that the polymer is extracted from the PTFE matrix to create pores in the tubular extrudate. In particular, the Examiner specifically states that "extraction of the polymer will create pores." The Examiner further asserts that the extractable polymer taught by Mitchell is silicone.

Mitchell is directed to compositions having interpenetrating matrices. These compositions include a PTFE polymer network and a second polymer network of diorganosiloxy groups. The PTFE network is characterized by nodes interconnected by fibrils, which structure is known as drawn, or expanded, PTFE. Such expanded PTFE thereby exhibits a porous microstructure. In accordance with this teaching, nowhere in Mitchell is it disclosed, taught or suggested to use non-expanded PTFE. Moreover, because Mitchell teaches creation of pores by expansion, it accordingly fails to disclose, teach or suggest that the pores are created by extraction of the second polymer component from the PTFE network.

In contrast, Applicants' amended claims are directed to an IPN of non-expanded PTFE and an extractable polymeric material. Mitchell only teaches compositions containing expanded PTFE, and therefore, does not anticipate this element of Applicants' amended claims.

Further, Applicants' claims require compositions in which pores are created by an

extractable polymeric material. As such, the pores correspond to domains of the extractable polymer. Mitchell does not teach extraction of a polymeric material to create pores, but rather expansion of PTFE to create a porous structure. Unlike Applicants' compositions, Mitchell's porous structure is characterized by nodes and fibrils.

Moreover, Mitchell distinguishes prior art patents which remove materials to create porous articles. *See* Mitchell; Col. 1, lines 27-32. Mitchell states that such processes are "complicated and expensive." *See id.* Instead, Mitchell's object is to provide a material that is breathable, but impermeable to water. According to Mitchell, such material is achieved by stretching the PTFE to create a porous structure while simultaneously curing silicone. Therefore, the final product of Mitchell is an IPN of expanded PTFE and silicone. *See id.* at Col. 1, lines 15-18, Col. 3, lines 32-34. Because silicone is an integral part of the final product and Mitchell distinguishes prior art on the basis of material removal, Mitchell actually teaches away from removing silicone from the PTFE matrix. *See Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (citing *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994)) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant or if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant."). In fact, silicone removal would destroy the intent and purpose of Mitchell's invention.

Although Mitchell mentions extraction in Table 5, this technique merely is used to determine the level of crosslinking in the IPN. There is no suggestion that extraction creates pores. Therefore, Mitchell not only fails to provide for, but even teaches away from a porous structure in which the pores correspond to domains of an extractable polymer. As such, Mitchell also fails to anticipate this recitation of Applicants' amended claims.

In view of the above, Mitchell cannot anticipate Applicants' amended claims 1, 3 and 21. Applicants' respectfully request reconsideration and withdrawal of this rejection.

**U.S. Patent No. 4,657,544 to Pinchuk**

Claims 1, 3 and 21 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,657,544 to Pinchuk (hereinafter "Pinchuk"). Applicants respectfully traverse the rejection on the basis that Pinchuk fails to disclose each and every element of Applicants' claims.

The Examiner contends that Pinchuk discloses a medical device, particularly a vascular graft, which is a tubular extrudate. The Examiner further contends that the medical device is an IPN including a PTFE matrix having an extractable polymeric material distributed therein. The Examiner further asserts that Pinchuk discloses silicone, which is an extractable polymeric material. The Examiner admits that Pinchuk fails to teach or suggest extraction of the silicone from the PTFE matrix. The Examiner contends, however, that Pinchuk teaches extraction of salt from the matrix to create pores, and thus, Pinchuk's end product is the same as recited in Applicants' claims.

Pinchuk is directed to a cardiovascular graft formed from a two component biocompatible polymer system. The two component polymer system contains a polymer resin, which is polyurethane, silicone or PTFE, and a curing agent. Contrary to the Examiner's allegations, however, nowhere in Pinchuk is it disclosed, taught or suggested to form an IPN of PTFE and silicone. Pinchuk does not even suggest a mixture of PTFE and silicone as separate polymer networks, let alone an interlacing network of the two polymers. Therefore, Pinchuk does not provide nor even suggest an IPN, as described above. Because Applicants' compositions require an IPN, Pinchuk fails to anticipate this element of Applicants' claims.

Furthermore, the polymer system of Pinchuk also includes salt crystals mixed therein, which are extracted to create pores. The pores in Pinchuk are created by and correspond to the salt crystals. In particular, Pinchuk explains that "the size and shape of the pores . . . are dictated by the choice of the specific inorganic salt that is compounded with the polymer system." See Pinchuk; Col. 4, lines 28-31. Therefore, Pinchuk teaches pores that correspond to salt crystals,

which are not an extractable polymer. Pinchuk thereby fails to disclose, teach or suggest pores that correspond to domains of an extractable polymeric material as recited in Applicants' claims.

Because Pinchuk fails to disclose, teach, or suggest an IPN including PTFE and an extractable polymeric component, as well as pores created by the extractable polymer, it cannot anticipate Applicants' claims. As such, Applicants respectfully request reconsideration and withdrawal of this rejection.

**Applicants' Response to Rejections under 35 U.S.C. §103**

Claim 2 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zilla in view of U.S. Patent No. 5,639,278 to Dereume et al. (hereinafter "Dereume"). Applicants respectfully traverse the rejection.

In addressing Zilla as a §102 reference, Applicants have already described in detail that Zilla does not provide nor even suggest a medical device having an IPN including PTFE and an extractable polymeric component. For the sake of brevity, Applicants will not repeat the discussion on Zilla.

For the same reasons that Zilla fails as a reference under 35 U.S.C. §102, the combination of Zilla and Dereume fail as a proper combination under 35 U.S.C. §103. Dereume is cited only for its teachings of combining a stent and a graft together and fails to teach or suggest anything of any relevance to the present invention as recited in the amended claims. Dereume clearly fails to cure the deficiencies of Zilla. The combination of Zilla and Dereume therefore fails to disclose each and every element of the claimed invention.

Withdrawal and reconsideration of the rejection is therefore respectfully requested.

In view of the foregoing, Claims 1-3 and 21-24 are now believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited.

Applicants: Girton et al.  
Application No: 10/002,521  
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If the Examiner has any questions regarding this Response, she is encouraged to contact the undersigned attorney.

Respectfully submitted,



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